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Changes of radiopacity around implants of different lengths: Five-year follow-up data of a randomized clinical trial

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Abstract: OBJECTIVE To follow-up the radiographic changes in peri-implant bone of short (6 mm, test group) and long (10 mm, control group) single-unit implants five years after loading. MATERIALS AND METHODS Forty-three implants of the test and 44 implants of the control group could be reassessed from 96 originally included implants. Standardized areas of interest (AOI) were defined in the peri-implant bone at pre-defined locations at mid-length on both sides of the implants, and at the apex. An arbitrary mean grey scale value (GSV) was calculated for the AOI after brightness calibration of the radiographs. Changes for GSV were calculated and tested for possible inter- and intra-group differences using the Mann-Whitney and Wilcoxon tests. RESULTS The calculated intra-group differences between baseline and 5 years in the test group accounted for 2.4 ± 19.6 (i.e. slight brightening) and -6.2 ± 20.2 for the control group (i.e. slight shading), which resulted in a statistically significant difference in GSV change ($p < .05$). Crown-to-implant ratio was the only parameter showing an effect on GSV change ($p = .001$). CONCLUSIONS Assessing conventional radiographs, longer implants showed a slightly stronger change of radiopacity of the peri-implant bone (slight loss of density) than short ones (slightly enhanced density) after five years of loading.

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Randomized Clinical Trial

Bone density changes around implants of different lengths. Five-year follow-up data of a randomized clinical trial

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Running title: *Peri-implant bone density change after 5y*

Keywords: bone level, dental implants, RCT, bone remodelling, radiography

Conflict of interest

All authors declare not to have financial or elsewise relation that might bear a conflict of interest.

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Abstract

Objectives: To follow-up the radiographic changes in peri-implant bone density of short (6 mm, test group) and long (10 mm, control group) single-unit implants five years after loading.
Materials and Methods: Forty-three implants of the test and 44 implants of the control group could be re-assessed from 96 originally included implants. Standardized areas of interest (AOI) were defined in the peri-implant bone at pre-defined locations at mid-length on both sides of the implants, and at the apex. An arbitrary mean grey scale value (GSV) was calculated for the AOI after brightness calibration of the x-rays. Changes for GSV were calculated and tested for possible inter- and intragroup differences using the Mann-Whitney and Wilcoxon test.
Results: The calculated intra-group differences between baseline and five years in the test group accounted for 2.4 ± 19.6 (i.e. slight brightening) and -6.2 ± 20.2 for the control group (i.e. slight shading), which was a statistically significant difference in GSV change ($p < 0.05$). Crown-to-implant ratio was the only parameter showing an effect on GSV change ($p = 0.001$).
Conclusions: Assessing conventional radiographs, longer implants showed a stronger change of peri-implant bone density (slight loss) than short ones (slight brightening) after five years of loading.

Scientific rationale for study: Previous data have shown a significant increase in radiographic peri-implant bone density around short implants after 1-3y. In this study changes in density after 5y were assessed.
Principal findings: While no group showed significant changes in radiographic bone density after 5y, a significant difference between the groups were observed with a pronounced loss of density around the longer implants.
Practical implications: Previously supposed stronger corticalization of peri-implant bone around short implants does not seem to be relevant after an observation time of 5 years.

Introduction

Dental implants have become a reliable standard treatment option to replace missing teeth(Benic et al. 2017, Jung et al. 2012). Success rates over 10 years and more are high, even when strict criteria are applied for assessment(Clementini et al. 2012, Moraschini et al. 2015). Nevertheless, implant failure and loss is clinical reality (Moraschini and Barboza 2016, Sendyk et al. 2017). Among different reasons for failure peri-implantitis is one of the most frequent (Jung et al. 2012, Muñoz et al. 2018) and – since gold standards for reliably successful therapy are still missing (Heitz-Mayfield and Mombelli 2014) – most dreaded ones. Biofilms, which colonize non-shedding implant surfaces represent the scientifically accepted primary etiologic factor for peri-implantitis(Salvi et al. 2017). Clinically, biofilms cause a marginal inflammation which results in mucosa and – at a later stage – resorption of the marginal peri-implant bone(Ramanauskaite and Juodzbalys 2016). Other radiographic changes than the marginal bone level can be observed on the x-ray over the years in function. Involving processes like tissue deposition, maturation and removal bone undergoes constant remodelling(Seeman and Delmas 2006, Gotfredsen et al. 2001). Over time, a pronounced radiographic density of the peri-implant bone on x-ray images was reported (Sahrmann et al. 2017), clinically reflected in bone with a more cortical appearance(Chambrone et al. 2010). Even though remodelling and structural change has been less reflected in studies so far, bone homeostasis might play a distinct role in the aetiology of a particular kind of implant loss which have been described as loss after several years in function without a history of marginal inflammation(Sahrmann et al. 2016, Storelli et al. 2018). These implants have been shown to typically display a pronounced density of the peri-implant bone on x-rays and, clinically, sheathing around the whole circumference with a filmy layer of non-mineralized soft tissue.

Based on data from an ongoing randomized clinical trial assessing implants of different lengths, a pronounced radiologic bone density was determined around implant of the cohort with short implants after three years of loading as compared to the longer ones(Sahrmann et al. 2017). In addition, more implants got lost from this test group. None of them had ever shown marginal inflammation previously, putting the issue of a stronger degree of corticalization into the focus of interest. Today, data regarding the pronounced bone density on implants with relatively higher loading forces are still weak and limited to an investigation period of only three years (Sahrmann et al. 2017). In order to follow-up previous findings after three years of loading, it was the aim of the present study to assess the changes in bone density around implants of either 6 or 10 mm of length after five years. Our hypothesis was that bone density increase around short implants would be consolidated after five years of observation.

Materials and Methods

This study was based on a collective of a previously published randomized clinical trial comparing clinical success of implants of two different lengths (Sahrmann et al. 2016, Naenni et al. 2018). For that study the ethics approval from the local ethical committee of the University of Zurich was obtained (StV 07/13) and the study had been registered online (German Clinical Trial Registry DRKS00006290). In brief, patients were randomly allocated into either a group that received implants (Standard plus SLA®, Straumann, Basel, Switzerland) with a length of 10 mm (control group) or another with implants of 6 mm of length (test group).

Exclusion criteria involved heavy smokers (≥ 20 cigarettes per day) and the need for marginal bone augmentation. The surgical intervention was performed according to the manufacturer's instructions. All implants replaced posterior teeth of the upper or lower jaw and were loaded after 10 weeks with screw-retained porcelain-fused-to-metal single crowns.

Patients had one control visit per year, including oral hygiene instructions and professional cleaning of the whole dentition, based on an individual risk assessment. Detailed information regarding the clinical procedures and assessment is given in a publication of the clinical results after three years (Sahrmann et al. 2016).

X-ray assessment

For each patient immediately after mounting the crown a custom-made individual x-ray splint was fabricated which allowed for exact repositioning of x-ray tube and film at all follow-up visits.

X-ray images were taken at the day of implant loading and after 1, 2, 3 and 5 years. Diagora Soredex plates size 2 (Soredex, Tuusula, Finland) were used at a voltage of 70 kV and 0.05 s for lower premolars, 0.08 s for lower molars and 0.1 s for upper molars.

For each x-ray a distance on 5.5 cm between the 10 cm long tube and the film was maintained using a plate holder system (MA Dental AG, Busswil, Switzerland).

In order to assess the arbitrary grey scale value (GSV) of the peri-implant bone three areas of interest (AOI) of 12 pixel feed size were defined on the baseline x-ray using the program Keynote (Vs. 8.3, Apple Inc., California, USA). One field was set at the implant's apex and two on each side at half height of the rough part of the implant body. Care was taken to place the areas as close as possible to the implant, however strictly excluding any "bright" implant-related pixel. In addition, two calibration areas were defined in central dentine or composite areas of neighbouring teeth, which supposedly would not change their brightness in the course of the years. These control areas were used to calibrate the 5y image for brightness.

The x-ray images five years after loading was then superimposed with the baseline pictures. If needed, superimposition was adapted only by slight rotation or moving. A digital mask containing the AOI and the implant contour of the baseline picture was created and copied on the five year image (see Figure 1).

The x-rays with respective AOI were transferred into ImageJ (Vs. 1.46r, National Institute of Health, USA) and the grey scale values were assessed using the *Analyze* > *measure* tool of the program. The indicated *mean* value was recorded as arbitrary grey scale value.

Statistics

Possible differences between the groups in the distribution of dichotomous variables like sex, smoking and history of periodontitis were tested by Pearson's chi square test. Grey scale value data sets were tested for normal distribution with Shapiro-Wilk-test and equality of variances by the Levene-test. Possible differences between the groups were assessed with t-test for unpaired variables in case of normal distribution and by Mann-Whitney test if skewed distribution was found. Possible intra-group differences after 5 years were assessed with t-test for paired samples or Wilcoxon test, accordingly. Negative values indicated a loss in peri-implant density while positive values showed increased density.

In order to test for possible effects of the crown-to-implant ratio, sex, smoking, history of periodontitis and implant length a random effect model was used. For each test the level of significance was set at 0.05. All tests were performed in SPSS (SPSS Statistics Vs. 23, IBM, NY, USA).

Results

After five years of implant loading 86 of originally 96 patients, 43 from the test group and 44 from the control group, were reassessed. Four patients had lost their short implants within the first four years and further 6 patients could either not be contacted or were unable to present themselves for follow up due to personal reasons. Sex distribution, cases with a history of periodontitis, smoking status and localization showed no significant intergroup differences (see Table 1). The crown-to-implant ratio with 1.75 ± 0.30 for the test implants and 1.03 ± 0.21 for the controls turned out to be statistically significantly different ($p = 0.02$) between the groups (Fig. 2).

With equally distributed data for the grey scale values and their variances, tests for normal data distribution were used to test for possible differences. Short implants, with 80.6 ± 27.5 at baseline and 83.1 ± 31.1 after five years did not show a significant change for the grey scale values over time. Likewise, implants of 10 mm missed to show a significant loss of density in the peri-implant bone for an within an ace ($p = 0.055$) with 98.9 ± 32.5 at baseline and 92.7 ± 31.3 after five years of observation. The change during the five years of observation resulted to be significantly different between the groups with 2.4 ± 19.6 for the test group and -6.2 ± 20.2 for the controls ($p = 0.046$).

Testing for possible effects of sex, smoking and history of periodontitis on grey scale values no significant impact was found for any of these effect parameters. Only crown-to-implant ratio turned out to significantly influence GSV ($p < 0.001$).

A subgroup analysis of the data of the short implants lost without clinical signs of marginal inflammation showed a change in grey scale values of 5.0 ± 19.1 as compared to 2.3 ± 19.9 for the short implants still in function (see Table 2). T-test for unpaired data showed no significant difference to the whole cohort of short implants.

Discussion

Among different surrogate parameters radiographic density of peri-implant bone which reflects the degree of mineralization of the bony microstructure (Meunier and Boivin 1997) might provide valuable insight into the homeostasis of peri-implant implant health and thereby the prognosis of implants. In a previous study radiographs of a RCT with implants of different lengths were already analysed, and an increased “brightening” of peri-implant grey scale values was observed after 1, 2 and 3 years of loading (Sahrmann et al. 2017). In the present evaluation this parameter was reassessed after an observation period of five years.

For the test group GSV after 5 years of loading did not differ anymore from the respective values at implant insertion. For the implants of the control group with 10 mm of length, a loss of GSV indicating a higher translucency of the bone and therefore a lower degree of mineralization missed significance within an ace. Accordingly, the postulated hypothesis was refused.

At first glance the findings of the present study seem contradictory to the previously published results after 1 to 3 years of function. While no progressive mineralization around the short implants was observed, control implants showed actually less dense bone than at the time point of implant placement. However the actual analysis confirmed a trend already observed in the previously published data: While the increase of brightness for the GSV showed a maximum after the first year of loading for both groups, change of GSV medians from baseline to the respective years decreased during the following years. In this study the difference to baseline after five years turned out not to be significantly different. For the longer control implants there were no significant differences to the baseline GSV during the first three years, but mean differences to baseline decreased likewise over the years. With a continued decrease, difference of mean GSV reached statistical significance after five years and showed - for the first time - a slightly lower bone density than at baseline. These changes partly reflect an ongoing adaptationin the homeostasis of the local bone household and its capacity of physiological adaptations (Coelho et al. 2009, McCauley and Nohutcu 2002, Bergkvist et al. 2010). On the other hand, the fact that the difference in bone density to baseline had its maximum after the first year of loading before continuously dropping is not easy to explain: The linear regression model did not reveal any impact of clinical parameters like sex, smoking and history of periodontitis on the change of GSV after 5y of loading. Decreasing density after an initial rise might be interpreted as either an immediate reaction on mechanical manipulation by drilling and insertion (Dolan et al. 2015, Hobkirk and Rusiniak 1977) or as a potential foreign body reaction on the titanium surface (Albrektsson et al. 2014). None of these possibilities however is suitable to explain why the effect was more pronounced in the short implant group, given that trauma or surface exposition is supposedly higher for the longer implants (Hobkirk and Rusiniak 1977). A physiologic adaptation to the relatively high loading forces on the smaller bone-implant interface of the test implants during the first year of loading (Hadjidakis and Androulakis 2006, Rungsiyakull et al. 2011) seems reasonable - but neither can explain the loss of density during the following years.

In the previous study, an increase of peri-implant bone density was suggested to be an etiologic co-factor for the phenomenon of implant loss without any previous symptoms of marginal inflammation like marginal bone loss(Sahrmann et al. 2017). This hypothesis was formulated based on the observation by Abrahamsson et al. that along with the transformation from spongy, highly vascularized bone with a considerable proportion of cytokine rich bone marrow to highly mineralized corticalization bone tissue suffers the loss of biologic capacity, physiologically reflected by a quick turn-over and potential of physiologic adaptation (Abrahamsson et al. 2004, Abrahamsson et al. 2009, Bergkvist et al. 2010). In a sub-analysis for the implants that got lost without any symptoms of marginal inflammation mean values for GSV turned out to be twice as high as compared to those of the whole cohort of short implants. Albeit supportive to the hypothesis, the respective tests failed to prove any significant differences with regard to healthy short implants due to small statistical power of only four lost implants.

Important to state is the fact that the cohort has not been exactly the same like the one of the previously published study with an investigation period of up to three years. While the number of analyzed patients was almost the same three patients were not available for the five year assessment, while another two patients missed the one-to-three year examination but were available after 5 years. Nevertheless, this insignificant discrepancy is unlikely to account for the different outcomes in the present evaluation.

While the present study showed that crown-to-implant ratio had an impact on radiographic bone density a recently published analysis tested for a possible effect of crown-to-implant ratio on the marginal bone level but did not prove any clinical impact (Guljé et al. 2016). Within a range of 0.86 to 2.14 (thereby covering the ratios for both test and control implants of the present analysis) the crown-to-implant ratio seems not to have an effect on biological or technical complications (Meijer et al. 2018). Any clinical relevance of the difference in bone density after 5 years of loading therefore appears to be questionable.

Conclusions

A pronounced corticalization of peri-implant bone around short implants is not observable on standardized conventional radiographs. On the other hand peri-implant bone around longer implants showed a pronounced loss of density as compared to short implants. Future observations should assess a possible clinical impact.

Clinical relevance

Scientific rationale for study: Previous data have shown a significant increase in radiographic peri-implant bone density around short implants after 1-3y. In this study changes in density after 5y were assessed.

Principal findings: While no group showed significant changes in radiographic bone density after 5y, a significant difference between the groups were observed with a pronounced loss of density around the longer implants.

Practical implications: Previously supposed stronger corticalization of peri-implant bone around short implants does not seem to be relevant after an observation time of 5 years.

Acknowledgement

The current study is part of and in parts identical (assessment of radiographs) with a master's thesis: " Änderung der radiologisch messbaren peri-implantären Knochendichte über einen Zeitraum von 5 Jahren bei Implantaten unterschiedlicher Länge " by B. Sluka, performed at the University of Zurich, Switzerland.

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Table and Figure legends:

Table 1 Patient and implant characteristics at baseline

[A] Pearson's chi-square test
[B] t-test for unpaired samples

Table 2 Changes in GSV from baseline to 5 years in function

GSV – Grey Scale Value, bold p-value indicates statistically significant difference between test and control implants
[A] t-test for unpaired samples

Fig. 1 X-rays of short (A and B) and long (C and D) implants at baseline (A and C) and after five years of loading (B and D).

Areas of interest (AOI) are indicated with C for calibration areas and T for test areas within the peri-implant bone, namely at the implant's apex (T2) and at half length mesially and distally (T 1 and 3).

Fig. 2 Difference of mean arbitrary grey scale values for 6 mm long test and 10 mm long control implants between baseline and after 5 years of loading.

Bold horizontal lines indicate medians, boxest he interquartile range. Whiskers indicate 95% confidence intervals. Test group contains (n = 43) short implants of 6 mm, controls (n= 44) of 10 mm.

Table 1 Patient and implant characteristics at baseline

Patient- and implant characteristics	Short (6 mm)	Control (10 mm)	p-value
Male/female[A]	23/19	23/21	0.83
Smokers[A]	13	12	0.81
History of peri-implantitis[A]	25	21	0.29
Crown-to-implant ratio [B]	1.75±0.30	1.03±0.21	**0.02**
Localization[A]			
Upper molars	3	7	
Upper premolars	9	15	
Lower molars	12	4	
Lower premolars	18	7	
			0.68

[A] Pearson's chi-square test
[B] t-test for unpaired samples

Table 2 Changes in GSV from baseline to 5 years in function

	Control (10 mm)	Short (6 mm)	p-value	Short lost (6 mm)
Change (GSV)	-6.2 ± 20.2	2.3 ± 19.6	**0.046**[A]	5.0 ± 19.1

GSV – Grey Scale Value, bold p-value indicates statistically significant difference between test and control implants

[A] t-test for unpaired samples

Fig. 1 X-rays of short (A and B) and long (C and D) implants at baseline (A and C) and after five years of loading (B and D).

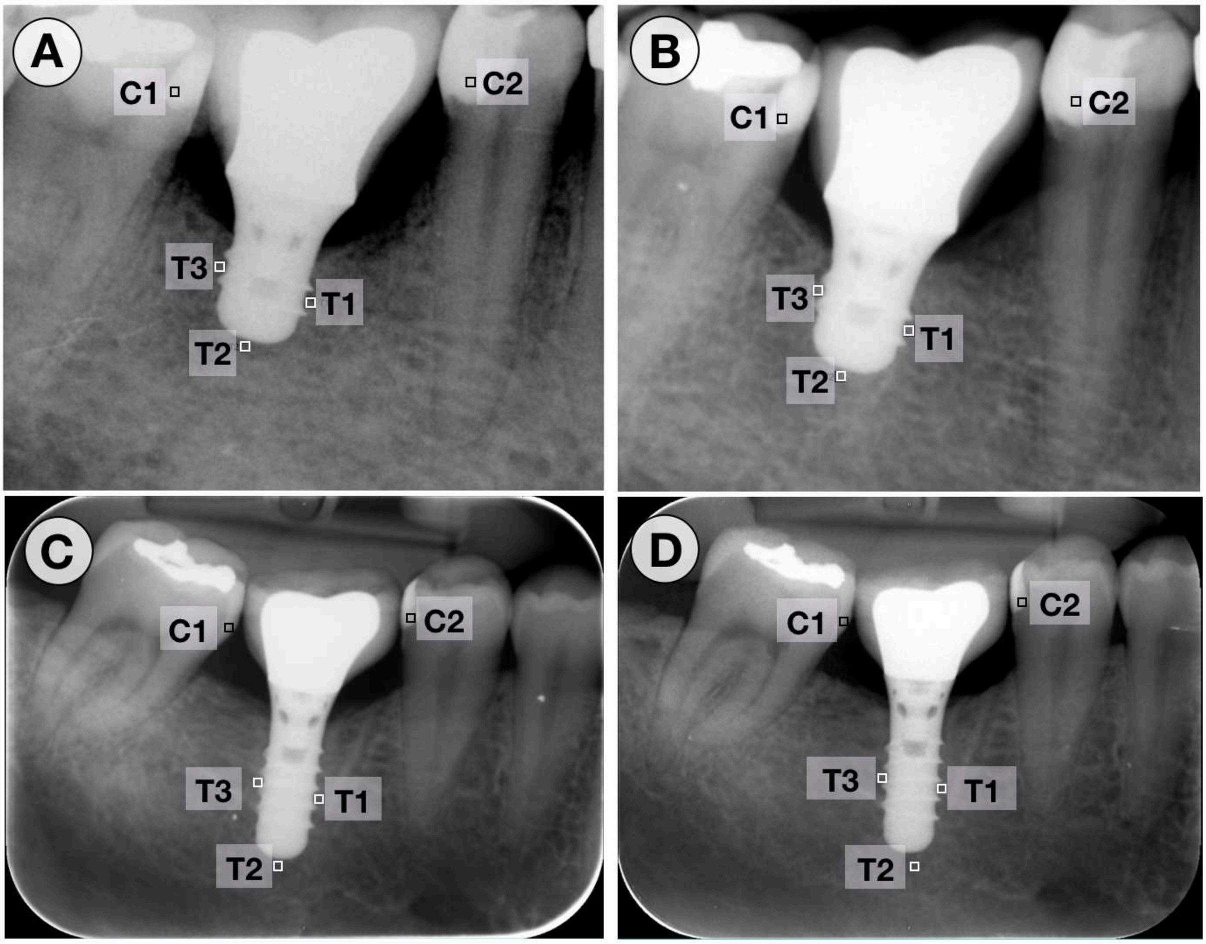

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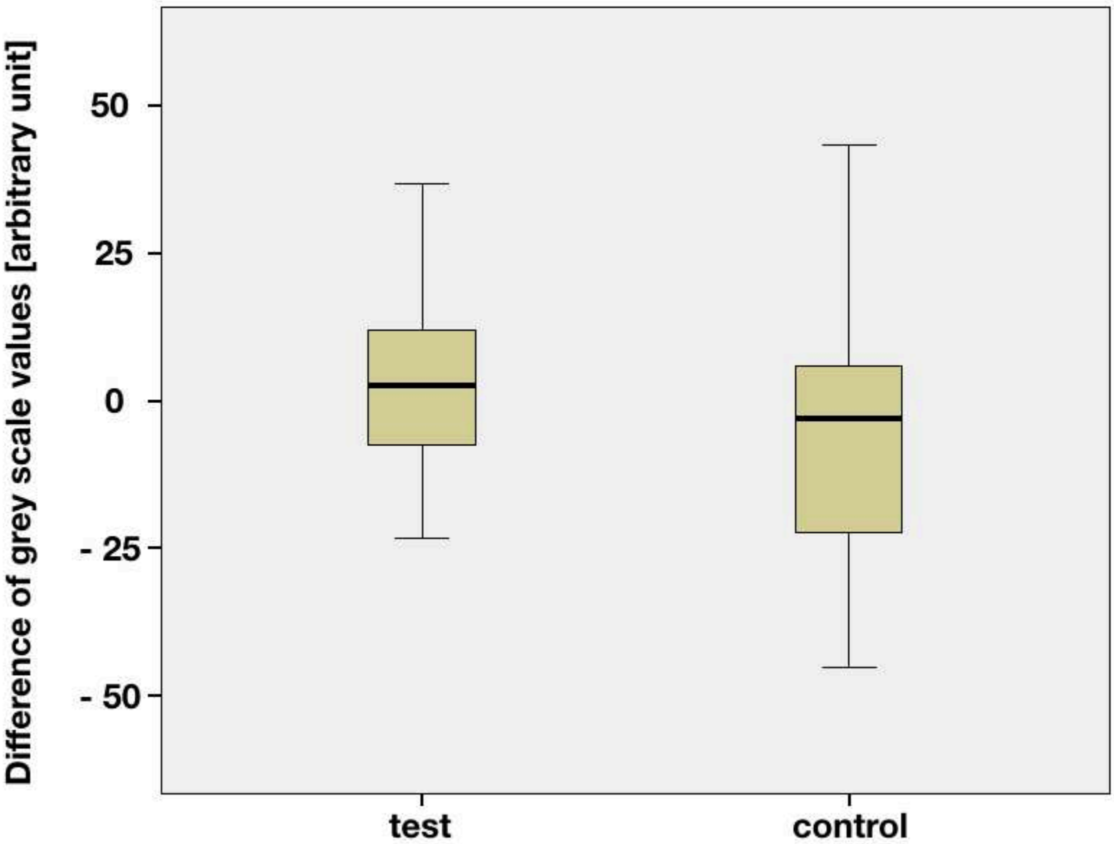
Fig. 2 Difference of mean arbitrary grey scale values for 6 mm long test and 10 mm long control implants between baseline and after 5 years of loading.



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